



September 1, 2011

## **New Data Suggest Veracyte's Afirma® Gene Expression Classifier Cost-Effectively Resolves Inconclusive Thyroid Nodule FNA Biopsy Results**

South San Francisco, Calif. --- September 1, 2011 --- Veracyte, Inc., a molecular diagnostics company pioneering the emerging field of molecular cytology, today announced that new data from researchers at Johns Hopkins University School of Medicine suggest that routine use of its Afirma® Gene Expression Classifier for clarifying inconclusive results on thyroid nodule fine needle aspiration (FNA) samples will improve patient care and save the healthcare system money. According to the economic impact study, nationwide use of the company's test would reduce the number of surgeries on patients with benign thyroid nodules by 74%, or 50,000 each year, and would provide more than \$600 million in direct medical savings over five years. The study appears [online](#) in the *Journal of Clinical Endocrinology & Metabolism* and is scheduled for publication in the journal's November print issue.

"The clinical and economic impacts of implementing this new technology are, in fact, similar in magnitude to those that accompanied the introduction almost 40 years ago of FNA cytology to differentiate between benign and malignant thyroid nodules," said study author Paul W. Ladenson, M.D., professor of endocrinology and metabolism and director of the Division of Endocrinology and Metabolism at the Johns Hopkins Medical Institutions. "We found that, even when we assessed a wide range of possible scenarios in our economic model, 93% of our projections using the gene expression test actually reduced costs while improving health outcomes. This is a rare finding for implementation of a novel management strategy."

The study was conducted using a Markov economic model to simulate costs over five years of managing adult patients with thyroid nodules whose FNA results are deemed inconclusive by cytology. The study compared direct medical costs using current practice, which relies on cytology alone, with hypothetical use of Veracyte's Afirma Gene Expression Classifier, which classifies as benign or suspicious for malignancy those thyroid nodule FNA samples deemed indeterminate by cytology. The analysis did not include indirect costs, such as time lost at work, decreased productivity or money spent on healthcare outside of the medical setting.

In addition to reducing the number of surgeries on patients with benign nodules, the authors found that routine use of the Afirma Gene Expression Classifier on indeterminate cases increased to 54% the likelihood

that patients who go to surgery will actually prove to have cancer, from 35% using current practice. There was no increase in missed cancers using the gene expression test.

"These findings add to the evidence demonstrating that our Afirma Gene Expression Classifier can enable doctors to make better and more efficient treatment decisions that improve care for thyroid patients and provide cost savings to the healthcare system," said Bonnie Anderson, Veracyte's cofounder and chief executive officer. "We look forward to continuing to make our test available to doctors and their patients across the country."

The Afirma Gene Expression Classifier is part of Veracyte's Afirma Thyroid FNA Analysis, a novel solution for improved accuracy in thyroid nodule diagnosis. This comprehensive approach combines expert cytopathology assessment along with the company's genomic test, which clarifies as either benign or suspicious for cancer those thyroid nodule FNA results initially deemed indeterminate by cytopathology. Previous multicenter studies have shown the test to have a negative predictive value of greater than 95%. Veracyte began making its solution available earlier this year to endocrinologists around the country.

Thyroid cancer is the fastest-growing cancer in the U.S., with an estimated 44,670 new cases per year. Thyroid FNAs, a procedure conducted in the doctor's office in which a needle is inserted into the suspicious nodule to extract cells for examination under a microscope, are typically used to rule out cancer. An estimated 450,000 thyroid nodule FNAs are performed in the U.S. each year, but they are challenging to interpret, producing inconclusive results in up to 30% of cases. Current guidelines recommend that most patients with inconclusive thyroid FNAs go to surgery to remove all or part of their thyroid. This approach is invasive, costly and can result in lifetime hormone therapy for the patients. Inconclusive results, however, carry only a 20-30% chance of malignancy.

### **About Veracyte**

Veracyte, Inc., based in South San Francisco, Calif., is pioneering the emerging field of molecular cytology, applying molecular biomarkers to cytology samples in order to improve cancer diagnosis by clarifying indeterminate results obtained from current

methods. The company aims to enable doctors to make more informed treatment decisions that improve patient care and provide cost savings to the healthcare system. The company utilizes rigorous science and an extensive, multi-center clinical program throughout discovery and development. Veracyte is privately held and funded by Domain Associates, Kleiner Perkins Caufield & Byers, TPG Biotech and Versant Ventures. For more information, visit [www.veracyte.com](http://www.veracyte.com).

**Media Contact:**

Tracy Morris

650-473-1272 (o)

650-380-4413 (c)

[tracy.morris@veracyte.com](mailto:tracy.morris@veracyte.com)

Send Veracyte media related inquiries to [media@veracyte.com](mailto:media@veracyte.com).